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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,978	04/25/2001	Susana Salceda	DEX-0172	3638

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EXAMINER	
AEDER, SEAN E	
ART UNIT	PAPER NUMBER
1642	

NOTIFICATION DATE	DELIVERY MODE
04/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	09/763,978	SALCEDA ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,21-28 and 35-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 21-28, and 35-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 1/9/09 in response to the Office Action of 7/9/08 are acknowledged and have been entered.

Claims 14, 21-28, and 35-49 are pending and are currently under examination.

Response to Arguments

35 USC § 101 and 35 USC § 112 Claim Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 21-28, and 35-49 remain rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a substantial utility or a well established utility, for the reasons stated in the Office Action of 5/17/07, the reasons stated in the Office Action of 10/22/07, the reasons stated in the Office Action of 7/9/08, and for the reasons set-forth below. Further, claims 14, 21-28, and 35-49 remain rejected under 35 U.S.C. 112 first paragraph, because since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know *how to use* the claimed invention, for the reasons stated in the Office Action of 5/17/07 the reasons stated in the Office

Action of 10/22/07, the reasons stated in the Office Action of 7/9/08, and for the reasons set-forth below.

The Office Action of 7/9/08 contains the following text:

"The claims are drawn to isolated antibodies or antibody fragments that bind specifically to a protein encoded by polynucleotide SEQ ID NO:1 or to fragments of a protein encoded by SEQ ID NO:1 and a method for binding said antibodies to said protein or to fragments of said protein.

As stated in the Office Action of 5/17/07, the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1. Thus, the specification does not provide enough information to indicate for which proteins the claimed antibodies are specific. Therefore, the specification clearly does not describe a utility for antibodies with unknown specificity.

In the Response of 8/17/07, Applicant reiterates previously-presented arguments. Applicant states that Examiner's suggestion that the protein encoded by SEQ ID NO:1 is not implicit in the teachings of the specification because multiple reading frames are identified using the tools available and one of skill in the art would have no reason to assume that the larges open reading frame (ORF) identified by a computer program would be the protein encoded by SEQ ID NO:1 is indicative of the Examiner's failure to weigh all the evidence before him. Applicant further states that the longest ORF of SEQ ID NO:1 begins with a Kozak consensus sequence at the 5' proximal ATG in SEQ ID NO:1, the initiator codon for the majority of mRNAs. Applicant further states that both consensus sequences and 5'-proximal ATG are well known characteristics of coding sequences of nucleic acids and therefore do not need to be expressly outlined in the specification. Applicant cites MPEP 2164.05 and states that the specification need not disclose what is well known to those of skill in the art and preferably omits that which is already available to the public. Applicant further cites Dr. Salceda's Declaration, which states "we know that the open reading frame in the forward direction of SEQ ID NO:1 would be a frame encoding a Methionine near the 5' end, encode many amino acids and terminate with a stop codon". Applicant further states that submitted with this declaration are data generated from ORF Finder program, which lists the longest open reading frame first when displaying the results. Applicant concludes: "Thus, contrary to the Examiner's suggestion, one of skill in the art does have reason to believe, absent evidence otherwise, that the largest open reading frame identified by a computer program for a selected nucleic acid sequence is the ORF encoding the protein".

The amendments to the claims and the arguments found in the Reply of 8/18/07 have been carefully considered, but are not deemed persuasive. In regards to the argument that the Examiner did not weigh all the evidence before him, the Examiner *has* weighed all the evidence before him and has addressed all said evidence in the Office Actions of 1/3/05, 6/22/05, 12/28/05, 7/28/06, and 5/17/07.

In regards to arguments that protein sequences and/or open reading frames were routinely obtained by those of skill in the art at the time of filing based upon

identifying ATG start sequences and Kozak consensus sequences and therefore do not need to be expressly outlined in the specification, this guidance and essential information was not provided in the originally filed application. Further, Kozak (The Journal of Cell Biology, 1991, 115(4):887-903) teaches that Kozak consensus sequences are not found at the start of *every* open reading frame (see right column of page 887 and left column of page 888, in particular); rather, they are the most frequently occurring sequences flanking functional initiator codons of open reading frames. Further, SEQ ID NO:1 contains numerous ATG "start sites" and the originally filed application gives no guidance for identifying which of said ATG "start sites" marks the 5' end of an open reading frame. Further, Kozak sequences are not specifically *defined* sequences; rather, Kozak sequences are "non-random sequences" comprised of different nucleotides and are described by a "likelihood" of the order of said nucleotides within a sequence. Since Kozak sequences are not defined by one *specific* sequence, it is unclear whether the asserted Kozak sequence near position 62 is the only bona fide Kozak sequence in SEQ ID NO:1, a region encoding the middle of a protein encoded by SEQ ID NO:1, or a region outside of an open reading frame of SEQ ID NO:1. Further, it is noted that Dr. Salceda declared that the sequence of the protein encoded by SEQ ID NO:1 was based on said sequence being encoded by a long sequence with a Methionine near the 5' end and terminate with a stop codon, rather than being based on a sequence being flanked by a Kozak sequence. Therefore, it is clear from the record that identification of start sites based on Kozak sequences is not as routine as Applicant asserts.

In regards to the citation of MPEP 2164.05 and the statement that the specification need not disclose what is well known to those of skill in the art and preferably omits that which is already available to the public, proteins encoded by SEQ ID NO:1 were not well known to those of skill in the art and were not already available to the public. Further, the sequence of proteins encoded by SEQ ID NO:1 are not implicit in the teachings of the specification and/or in the teachings of the specification in light of the art. There were routinely-used methods at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence. However, as indicated in the figures provided with the Declaration, Applicants would identify multiple open reading frames using tools described in the art with SEQ ID NO:1. One of skill in the art would have no reason to assume that a particular potential ORF identified by a computer program would encode *the* protein encoded by SEQ ID NO:1. From the information provided in the specification, the protein of SEQ ID NO:1 may be encoded by other smaller open reading frames diagramed in the Declaration's figures. Therefore, since the specification does not identify "a protein encoded by polynucleotide SEQ ID NO:1", it cannot be determined to what the claimed antibody or antibody fragment will bind. Utility of an antibody specific for a protein that the specification did not adequately describe is irrelevant. Essentially, the specification does not describe what the protein *is*. Thus, there is no utility for the claimed antibodies, antibody fragments, or methods of using said antibodies or said antibody fragments.

In the Submission of 4/22/08, Applicant states that the instant specification meets the requirements of enabling how to use and establishing a specific, substantial and

credible utility with respect to the claimed invention. Applicant further presents a declaration by Dr. Sluss, which disagrees with the Examiner that utility of the claimed invention is dependent upon identification of "the" protein sequence or the open reading frame of SEQ ID NO:1 and indicates that overexpression of OVr110 mRNA in gynecological cancers demonstrates utility for the claimed invention. Applicant further states that it is clear from Dr. Sluss' Declaration that further research and development required to select antibodies useful as diagnostic cancer markers for Ovr110 was well established and routine by 1998. Dr. Sluss' Declaration further states that as of 1998, generating proteins and peptides encoded by a defined nucleic acid sequence such as SEQ ID NO:1 or its fragment was routine. Dr. Sluss' Declaration further states that as of 1998, generating antibodies for proteins and validating antibody-based diagnostic methods was routine.

The amendments to the claims and the arguments found in the Submission of 4/22/08 have been carefully considered, but are not deemed persuasive. In regards to the argument that the specification provides a specific, substantial and credible utility with respect to the claimed invention, the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1. Thus, the specification does not provide enough information to indicate for which proteins antibodies of the instant claims are specific. The specification clearly does not describe a utility for antibodies with unknown specificity. Further, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know *how to use* the claimed invention.

In regards to the declaration by Dr. Sluss, which disagrees with the Examiner that utility of the claimed invention is dependent upon identification of "the" protein sequence or the open reading frame of SEQ ID NO:1 and indicates that overexpression of Ovr110 mRNA in gynecological cancers demonstrates utility for the claimed invention, overexpression of Ovr110 mRNA in gynecological cancers demonstrates utility for Ovr110 mRNA and methods of detecting Ovr110 mRNA. Unlike disclosed Ovr110 mRNA, the specification does not provide enough information to indicate for which proteins antibodies of the instant claims are specific. While specificity for reagents used to detect Ovr110 mRNA is clear, the specification clearly does not describe a utility for antibodies with unknown specificity.

In regards to the arguments that it is clear from Dr. Sluss' Declaration that further research and development required to select antibodies useful as diagnostic cancer markers for Ovr110 was well established and routine by 1998, such antibodies or the specificity of such antibodies are not disclosed in the instant specification. Further, the sequence of proteins encoded by SEQ ID NO:1 are not implicit in the teachings of the specification and/or in the teachings of the specification in light of the art. There were routinely-used methods at the time of filing that would have enabled one of skill in the art to identify *potential* open reading frames from an mRNA sequence. However, as noted in Applicant's previous declaration by Dr. Salceda, Applicants would identify multiple open reading frames using tools described in the art with SEQ ID NO:1. One of skill in the art would have no reason to assume that a particular potential ORF identified by a computer program would encode *the* protein encoded by SEQ ID NO:1. Further,

screening methods proposed by Dr. Sluss' declaration to determine whether proteins encoded by potential open reading frames would generate antibodies that differentiate cancerous gynecological tissue from non-cancerous gynecological tissue would not necessarily bind proteins that are actually produced by SEQ ID NO:1 and such screening methods to identify antibodies is part of the inventive process to identify an antibody and not methods of "further research and development" for an identified invention. From the information provided in the specification, the protein of SEQ ID NO:1 may be encoded by other smaller open reading frames diagramed in Dr. Salceda's Declaration's figures. Therefore, since the specification does not identify "a protein encoded by polynucleotide SEQ ID NO:1", it cannot be determined to what the antibody of the claims will bind. Without disclosing identifying structural characteristics or binding specificities of the antibodies of the instant claims, said antibodies and processes of using said antibodies have not been invented or discovered in a manner supported by a specific and substantial utility or a well-established utility."

In the Reply of 1/9/09, Applicant presents arguments addressing the written description rejection. Applicant further argues that the disclosure states that antibodies raised against a protein encoded by SEQ ID NO:1 are useful in detecting gynecological cancers and lung cancers. Applicant further argues that evidence confirming utility of the claimed antibodies has been submitted. Applicant further argues that submitted declarations state that one of skill would know how to make and use the claimed invention based on the disclosure. Applicant further presents arguments that have been previously addressed. Applicant further argues that the examiner has failed to provide specific evidence or case law relevant to the instant fact situation to support the suggestion that without identifying for which protein the claimed antibodies are specific in the specification, the antibodies lack utility.

The arguments found in the Reply of 1/9/09 have been carefully considered, but are not deemed persuasive. It is noted that arguments addressing the written description rejection are addressed below. In regard to arguments that the disclosure

states that antibodies raised against a protein encoded by SEQ ID NO:1 are useful in detecting gynecological cancers and lung cancers, that evidence confirming utility of the claimed antibodies has been submitted, and that one of skill would know how to make and use the claimed invention based on the disclosure, the disclosure does not contain a written description of said antibodies for the reasons stated below. The specification does not describe the structure of the claimed antibodies, the specification does not describe the structure of polypeptides to which the claimed antibodies bind, and the specification does not disclose that the claimed antibodies have been deposited. Thus, there is no utility for the claimed antibodies, antibody fragments, or methods of using said antibodies or said antibody fragments because the claimed antibodies are not described in the specification and one of skill in the art would not know what to use.

In regards to the argument that the examiner has failed to provide specific evidence or case law relevant to the instant fact situation that the antibodies lack utility without identifying for which protein the claimed antibodies are specific in the specification, the Examiner agrees that there are numerous ways in which a specification can provide a written description of antibodies in a manner enabling one to make or use said antibodies. However, the instant specification does not disclose any of those ways. Further, the case law cited by Applicant in the Reply of 1/9/09 indicates that a written description of antibodies can be provided by a disclosed method of making an invention and the function of the invention (In re Hayes Microcomputer Products, Inc. Patent Litigation, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992). In the instant case, the specification does not disclose a method of making

the claimed antibodies and the function of the claimed antibodies, as the specification does not disclose the antigen which is required to make the claimed antibodies and the specification does not disclose the specific function of the claimed antibodies (such as which antigen the claimed antibodies bind). Further, the utility rejection is proper because the specification does not disclose the claimed antibodies and 35 U.S.C. 101 requires one to discover or invent a useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, to obtain a patent therefor. No such discovery or invention is disclosed due to a lack of written description of the claimed invention.

The rejection of claims 14, 21-28, and 35-49 under 35 U.S.C. 112 first paragraph, for failing to comply with the written description requirement, is maintained for the reasons stated in the Office Action of 5/17/07, the reasons stated in the Office Action of 10/22/07, the reasons stated in the Office Action of 7/9/08, and for the reasons set-forth below.

The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of antibodies or antibody fragments that bind specifically to a protein encoded by polynucleotide SEQ ID NO:1 or to fragments of a protein encoded by SEQ ID NO:1 and a method for binding said antibodies to said protein or to fragments of said protein.

The specification teaches SEQ ID NO:1. Neither the specification nor the prior art disclose the protein encoded by SEQ ID NO:1 because an open reading frame of SEQ ID NO:1 has not been identified and because the sequence of the protein has not been disclosed. Without knowledge of what SEQ ID NO:1 encodes, the specification does not provide enough information to indicate for which proteins the claimed antibodies are specific. Further, the specification does not disclose that the claimed antibodies have been deposited. Further, without disclosing an antigen, the specification does not disclose a method of generating the claimed antibodies.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The inventions at issue in Lilly were DNA constructs per se, the holdings of that case is also applicable to claims such as those at issue here. Further, disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of antibodies that encompass the genus nor does it provide a description of structural features that are common to the genus. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, the disclosure of SEQ ID NO:1 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25

USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). Further discussion of why it is unclear which polypeptide the antibodies are to bind can be found above and in the Office Actions of 1/3/05, 6/22/05, 12/28/05, 7/28/06, 5/17/07, and 7/9/08.

In the Reply of 1/9/09, Applicant repeats arguments addressed in previous Office Actions. Applicant further argues that neither a disclosure of the amino acid sequence for a protein encoded by SEQ ID NO:1 nor disclosure of the structure of the claimed antibodies should not be required in the instant situation. Applicant further argues that because an explicit disclosure of a nucleic acid sequence is not required when a polypeptide sequence is disclosed, it is improper to require explicit disclosure of a polypeptide sequence to which claimed antibodies bind when a nucleic acid sequence is disclosed. Applicant further argues that the facts of *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 are very different than the instant case because the claims in those cases were drawn to nucleic acid sequences for which no sequence information was set forth in the

patent application. Applicant further argues that the genetic code, coupled with reasonable predictability associated with a proximal ATG and Kozak sequence, establishes a strong structural correlation between a nucleic acid sequence and a protein encoded thereby. Applicant further states that the Courts have recognized that a strong structural correlation between a protein and antibodies raised thereto is well-established. Applicant further argues that one of skill in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from the recitation of its function.

The arguments found in the Reply of 1/9/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that neither a disclosure of the amino acid sequence for a protein encoded by SEQ ID NO:1 nor disclosure of the structure of the claimed antibodies should not be required in the instant situation, the Examiner agrees that there are multiple ways of showing possession of the claimed antibodies. Case law cited by Applicant in the Reply of 1/9/09 indicates that a written description of antibodies can be provided by a disclosed method of making an invention and the function of the invention (In re Hayes Microcomputer Products, Inc. Patent Litigation, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992). In the instant case, the specification does not disclose a method of making the claimed antibodies and the function of the claimed antibodies, as the specification does not disclose the antigen which is required to make the claimed antibodies and the specification does not disclose the specific function of the claimed antibodies (such as which antigen the claimed antibodies bind). Further, Example 13 of the Written

Description guidelines cited by Applicant in the Reply of 1/9/09 indicates that a written description of antibodies can be provided by disclosure of an antigen, deposit of the antibody, or describing an antibody structurally. In the instant case, the specification does not disclose an antigen to which the anybodies bind, does not disclose deposit of the antibodies, and does not disclose a structural description of the antibodies required for the claimed function.

In regards to the argument that it is improper to require explicit disclosure of a polypeptide sequence to which claimed antibodies bind when a nucleic acid sequence is disclosed because an explicit disclosure of a nucleic acid sequence is not required when a polypeptide sequence is disclosed, without disclosing a particular open reading frame of a nucleic acid sequence one of skill in the art would not know the protein sequence encoded by said nucleic acid sequence. Without knowledge of the protein sequence encoded by instant SEQ ID NO:1, one of skill in the art would not know which antigen to use in order to make the claimed antibodies.

In regards to the argument that the facts of *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 are very different than the instant case because the claims in those cases were drawn to nucleic acid sequences for which no sequence information was set forth in the patent application, no sequence of a protein encoded by SEQ ID NO:1 is disclosed in the instant application.

In regard to the arguments that the Courts have recognized that a strong structural correlation between a protein and antibodies raised thereto is well-established

and that the genetic code, coupled with reasonable predictability associated with a proximal ATG and Kozak sequence, establishes a strong structural correlation between a nucleic acid sequence and a protein encoded thereby, as noted in Applicant's previous declaration by Dr. Salceda, Applicants would identify multiple potential open reading frames using tools described in the art with SEQ ID NO:1. One of skill in the art would have no reason to assume that a particular potential ORF identified by a computer program would encode *the* protein encoded by SEQ ID NO:1. Further, while the Declaration of Dr. Salceda states that tools were available in 1998 to predict proteins, predict epitopes, and screen for antibodies of the instant claims, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

In regards to the argument that one of skill in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from the recitation of its function, one of skill in the art would not be able to predict the structure of the claimed antibodies based on recitation of a function of specifically binding a protein to which the specification does not provide a written description.

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642